IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
Clarksburg

ASTRAZENECA AB and **ASTRAZENECA PHARMACEUTICALS LP,**

Plaintiffs,

v.

CIVIL ACTION NO. 1:22-CV-35
Judge Bailey

MYLAN PHARMACEUTICALS, INC. and **KINDEVA DRUG DELIVERY L.P.,**

Defendants.

SEALED MEMORANDUM OPINION AND ORDER

This patent infringement case involves one (1) United States Patent issued to AstraZeneca AB and sold and distributed by AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"). Specifically, the patent at issue is U.S. Patent No. 11,311,558 ("the patent-in-suit"). AstraZeneca uses the pharmaceutical compositions and methods described in the patent to produce Symbicort®, a prescription drug approved for the treatment of inflammatory conditions/disorders, especially respiratory diseases such as asthma, chronic obstructive pulmonary disease ("COPD"), and rhinitis. The patent-in-suit shares a specification with U.S. Patent Nos. 7,759,328, 8,143,239, 8,575,137, and 10,166,247 that were the subject of two prior trials before Judge Keeley, but their claims have different scopes.

Pending before this Court are the following motions:

1. AstraZeneca's Motion for Summary Judgment [Doc. 164]; and

2. Defendants' Motion for Partial Summary Judgment [Doc. 156].

All the above motions have been fully briefed and are ripe for decision.

I. Background

According to AstraZeneca, 3M Company, through its 3M Drug Delivery Systems division, submitted Abbreviated New Drug Application ("ANDA") No. 211699 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of budesonide and formoterol fumarate dihydrate inhalation aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5 mcg ("Mylan's ANDA Products"). *See* [Doc. 1 at 4]. On August 17, 2018, 3M transferred certain interests in ANDA No. 211699 to Mylan Pharmaceuticals Inc. [Id.]. Thereafter, on May 1, 2020, 3M closed on a transaction whereby 3M sold substantially all of its drug delivery systems business to an affiliate of Altaris Capital Partners, LLC ("Altaris"). [Id.]. Following this transaction, Altaris launched Kindeva as an independent company, and all of 3M's activities relating to ANDA No. 21169 were transferred to Kindeva. [Id.]. Kindeva will manufacture Mylan's ANDA Products. [Id. At 4–5]. ANDA No. 21169 was approved on March 16, 2022.

In a letter dated August 30, 2018, Mylan notified AstraZeneca that it had filed ANDA No. 211699 seeking approval to market Mylan's ANDA Products prior to the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations for Symbicort. [Id. at 5]. In its letter, Mylan asserted that the '328, '239, and '137 patents are invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

In a second letter dated October 11, 2019, Mylan notified AstraZeneca that it had submitted a certification to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 211699 prior to the expiration of the '247 patent. [Id. at 5]. In its second letter, Mylan also asserted that the '247 patent was invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

The parties proceeded to trial on the '328, '239, and '137 patents (the "Trial Patents") in October 2020. [Id.]. Prior to trial, Mylan stipulated to infringement of the asserted claims of the Trial Patents. [Id.]. After a five-day trial, Judge Keeley entered judgment of nonobviousness as to each asserted claim. *See* ***AstraZeneca AB v. Mylan Pharms. Inc.***, 522 F.Supp.3d 200 (N.D. W.Va. Mar. 2, 2021) (Keeley, J.). The Court held that a person of ordinary skill in the art ("POSA") "would not have been motivated to select the specific formulation claimed by the patents-in-suit." ***Id***. at 219. The Court further found that the prior art "teaches away and does not render the claims obvious" because it "cut against the very goal a POSA would have been trying to achieve–a stable product with a consistent dose." ***Id***. at 220. Judge Keeley likewise found that "a POSA would not have had a reasonable expectation of success in creating a stable budesonide pMDI using HFA 227, PVP K25, and PEG-1000, much less when these ingredients were combined with formoterol." ***Id***.

Mylan appealed, and the Federal Circuit affirmed the Court's judgment of nonobviousness. ***AstraZeneca AB v. Mylan Pharms. Inc.***, 19 F.4th 1325, 1337–38 (Fed. Cir. 2021).[1]

In a letter dated March 8, 2022, AstraZeneca notified Mylan that the United States Patent and Trademark Office ("USPTO") allowed the pending claims of U.S. Patent Application No. 16/832,590 ("the '590 application"), which issued as the '558 patent on April 26, 2022. [Doc. 1 at 7]. In its letter, AstraZeneca notified Mylan of two items: (1) that its proposed generic Symbicort products infringe every limitation of the allowed claims and (2) that the allowed claims were substantially identical to the invention claimed in the U.S. Patent Application Publication No. 2021/0069215 ("the '215 publication"). [Id.].

On November 23, 2022, this Court issued its Memorandum Opinion and Order [Doc. 204] construing the following terms and phrases as follows:

1. "pharmaceutical composition" means "a formulation for therapeutic administration";
2. "formoterol" means "formoterol";
3. "budesonide or an epimer thereof" means "budesonide or an epimer thereof"; and
4. "about 0.001% w/w" means "approximately 0.001% w/w".

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[1] The Federal Circuit disagreed with the Court's construction of a term not at issue in most claims of the patent-in-suit (0.001%). The Federal Circuit vacated for further proceedings. Judge Keeley issued a Memorandum Opinion and Order Following Bench Trial on November 9, 2022, holding Mylan carried its burden of proving that the asserted claims are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and lack of written description. *See* Civ. Act. No. 1:18-CV-193 [Doc. 606].

In AstraZeneca's Motion for Summary Judgment, AstraZeneca requests this Court to grant summary judgment that Mylan infringes claims 1, 3, 4, and 7 of the patent-in-suit and enter final judgment in AstraZeneca's favor under 35 U.S.C. § 271(e)(4), and declaratory judgment in AstraZeneca's favor that the products described in Mylan's ANDA will infringe under 35 U.S.C. § 271(a), (b), (c), and/or (f). *See* [Doc. 164 at 1]. Moreover, AstraZeneca argues that if this Court rejects Mylan's construction of the claim term "pharmaceutical composition" as including a functional stability limitation, such as physical suspension stability, Mylan will be unable to prove by clear and convincing evidence that any asserted claim of the patent-in-suit is invalid because all of their invalidity defenses require the Court's adoption of Mylan's construction. *See* [Id. at 1–2].

In Mylan's Motion for Partial Summary Judgment, Mylan requests this Court to grant partial summary judgment in their favor with respect to Count I of the complaint because AstraZeneca does not allege and cannot show that Mylan committed an act of infringement under the provisions of § 271(e)(2). *See* [Doc. 156 at 1].

II. Standard of Review

The Supreme Court has encouraged the use of summary judgment to resolve disputes and to simplify issues before trial.

> Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to "secure the just, speedy and inexpensive determination of every action."

Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1) (citation omitted).

The Court of Appeals for the Federal Circuit has similarly recognized the benefits of summary judgment in patent cases.

> Summary judgment is as appropriate in a patent case as in any other. Where no genuine issue of material fact remains and the movant is entitled to judgment as a matter of law, the court should utilize the salutary procedure of Fed. R. Civ. P. 56 to avoid unnecessary expense to the parties and wasteful utilization of the jury process and judicial resources.

Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984).

Federal Rule of Civil Procedure 56 provides that summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The party seeking summary judgment bears the initial burden of showing the absence of any genuine issues of material fact. *See* ***Celotex Corp. v. Catrett***, 477 U.S. 317, 322–23 (1986). If the moving party meets this burden, the nonmoving party "may not rest upon the mere allegations or denials of its pleading, but must set forth specific facts showing there is a genuine issue for trial." ***Anderson v. Liberty Lobby, Inc.***, 477 U.S. 242, 248 (1986). A genuine issue exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." ***Id.*** "The inquiry performed is the threshold inquiry of

determining whether there is the need for a trial—whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." ***Id.*** at 250.

In reviewing the supported underlying facts, all inferences must be viewed in the light most favorable to the party opposing the motion. *See* ***Matsushita Elec. Indus. Co. v. Zenith Radio Corp.***, 475 U.S. 574, 587 (1986). Additionally, the party opposing summary judgment "must do more than simply show that there is some metaphysical doubt as to the material facts." ***Id.*** at 586. That is, once the movant has met its burden to show absence of material fact, the party opposing summary judgment must then come forward with affidavits or other evidence demonstrating there is indeed a genuine issue for trial. Fed. R. Civ. P. 56(c); ***Celotex Corp.***, 477 U.S. at 323–25; ***Anderson***, 477 U.S. at 248. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." ***Anderson***, 477 U.S. at 249 (citations omitted). Although all justifiable inferences are to be drawn in favor of the non-movant, the non-moving party "cannot create a genuine issue of material fact through mere speculation of the building of one inference upon another." ***Beale v. Hardy***, 769 F.2d 213, 214 (4th Cir. 1985). Further, "the plain language of Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." ***Celotex Corp.***, 477 U.S. at 322.

When faced with cross-motions for summary judgment, a district court is not required to grant judgment as a matter of law for one side or the other; rather, the court

must evaluate each party's motion on its own merits, taking care in each instance to draw all reasonable inferences against the party whose motion is under consideration. Wright, Miller, & Kane, *Federal Practice and Procedure:* Civil 2d § 2720.

III. Discussion

A. AstraZeneca's Motion for Summary Judgment[2]

i. Enablement

Section 112 of the Patent Act requires that, to be valid, a patent's specification must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C. § 112, ¶ 1. These three requirements, known as the "written description requirement," the "enablement requirement" and the "best mode requirement," are independent of one another and must all be satisfied for a patent to be valid. ***Univ. of Rochester v. G.D. Searle & Co., Inc.***, 358 F.3d 916, 921–22 (Fed. Cir. 2004).

Whether a patent's specification has met the enablement requirement is a question of law based on underlying factual determinations. ***Auto. Techs. Int'l v. BMW of N. Am., Inc.***, 501 F.3d 1274, 1281 (Fed. Cir. 2007). "Because a patent is presumed to be valid,

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[2] A stipulation was filed by Mylan that Mylan "will agree that Mylan's ANDA products, if sold, would infringe the asserted claims under 35 U.S.C. § 271(a) and that those claims are not invalid under this Court's construction of 'pharmaceutical composition.'" *See* [Doc. 211 at 2]. Mylan, as a result, requests this Court to enter a final, appealable judgment finding the asserted claims of the '558 patent would be infringed under § 271(a) and that they are not invalid under this Court's construction of "pharmaceutical composition." *See* [id.].

the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence." ***Id***.

The "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." ***AK Steel Corp. v. Sollac & Ugine***, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Importantly, the "full scope" of the invention must be enabled; merely enabling one single embodiment of the invention does not necessarily satisfy the enablement requirement for more broadly written claims. ***Auto. Techs.***, 501 F.3d at 1285.

In this case, AstraZeneca argues that Mylan cannot prove by clear and convincing evidence that the claims at issue lack enablement. *See* [Doc. 164-1 at 13]. In support, AstraZeneca asserts that Mylan and its expert witness, Dr. Smyth, chose not to advance any argument that the claims of the patent-in-suit are invalid under AstraZeneca's proposed construction.

In response, Mylan argues first, there are issues of fact regarding enablement of useful formulations that still preclude summary judgment. *See* [Doc. 174 at 11–18]. Second, Mylan argues there are issues of fact regarding enablement of solution formulations that preclude summary judgment. *See* [Id. at 19].

In reply, AstraZeneca reasserts many of its arguments from its Motion and further argues there is no dispute of material fact over enablement. *See* [Doc. 182 at 16–18].

To aid a court in determining whether claims such as these have been sufficiently enabled to avoid undue experimentation, the Federal Circuit has provided eight factors. Called the "***Wands*** factors," these include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Here, relying on the ***Wands*** factors, this Court concludes that there are material factual disputes as to whether a person of ordinary skill in the art could have replicated the results of the asserted claims without undue experimentation. *See* ***Wands***, 858 F.2d at 737.

Given that genuine questions of fact remain as to the ***Wands*** factors, this Court is precluded from granting summary judgment. Thus, the Court **DENIES** AstraZeneca's motion for summary judgment on this issue.

ii. Written Description

The "written description" requirement is designed to put future inventors on notice of the existence and scope of an invention and to prevent inventors from claiming ownership over more than they rightfully invented. Accordingly, the description must "reasonably convey" to one skilled in the art that the inventor possessed the claimed invention at the time of the filing date. *See, e.g.*, ***Augustine Medical, Inc. v. Gaymar Indus.***, 181 F.3d 1291, 1302 (Fed. Cir. 1999); ***Vas-Cath Inc. v. Mahurkar***, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991); ***Rambus, Inc. v. Infineon Technologies AG***, 330 F.Supp.2d 679 (E.D. Va. 2004) (Payne, J.); ***Affymetrix, Inc. v. PE Corp.***, 306 F.Supp.2d 363, 370

(S.D. N.Y. 2004). Whether a patent satisfies this requirement is "a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" ***Amgen Inc. v. Hoechst Marion Roussel, Inc.***, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (quoting ***Enzo Biochem v. Gen-Probe, Inc.***, 296 F.3d 1316, 1324 (Fed. Cir. 2002)); *see also* ***Vas-Cath, Inc.***, 935 F.3d at 1562 (stating that "the precedential values of cases in this area is extremely limited").

"[A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." ***Ariad Pharms., Inc. v. Eli Lilly and Co.***, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) (citing ***Regents of the University of California v. Eli Lilly & Co.***, 119 F.3d 1559 (Fed. Cir. 1997)).

"[A]n adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." ***Id.*** (citations omitted).

Because written description is a fact question, Mylan must show that no reasonable fact finder could return a verdict for AstraZeneca. ***Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.***, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (reversing summary judgment of no written description). Thus, Mylan must show that no reasonable jury could conclude that the patents "reasonably convey[ ] to those skilled in the art that the inventor[s] had possession of the claimed subject matter as of the filing date." ***Ariad***, 598 F.3d at 1351.

AstraZeneca argues that Mylan's written description defense mirrors its enablement argument. *See* [Doc. 164-1 at 19–21]. AstraZeneca asserts Dr. Smyth's opinion that the claims of the patent-in-suit lack adequate written description "has no basis absent adoption of his erroneous construction of 'pharmaceutical composition' as incorporating a functional stability requirement." [Id. at 20].

In turn, Mylan argues it can prove that all asserted claims lack written description under either party's construction of "pharmaceutical composition." *See* [Doc. 174 at 20–24]. Mylan asserts that "[t]here are . . . an immense number of claimed formulations that are undisclosed and unexplored in the specification, raising serious factual issues regarding whether a POSA would deem there to be an adequate written description to support the full scope of the claims." [Id. at 22].

Put simply, this issue raises a question of fact that must be resolved at trial. The standard is whether the description "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," ***Ariad***, 598 F.3d at 1351, and it is possible to meet that standard even where the patent does not describe the claimed process in detail. *See* ***Hynix Semiconductor Inc. v. Rambus Inc.***, 645 F.3d 1336, 1352 (Fed. Cir. 2011). Therefore, the Court **DENIES** AstraZeneca's motion for summary judgment on this issue.

iii. Indefiniteness

As explained by the Supreme Court of the United States:

> A patent is invalid for indefiniteness if its claims, read in light of the patent's specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.
>
> Section 112's definiteness requirement must take into account the inherent limitations of language. *See* ***Festo Corp v. Shoketsu Kinzoku Kogyo Kabushiki Co.***, 535 U.S. 722, 731 [(2002)]. On the one hand, some modicum of uncertainty is the "price of ensuring the appropriate incentives for innovation," ***id.***, at 732; and patents are "not addressed to lawyers, or even to the public generally," but to those skilled in the relevant art, ***Carnegie Steel Co. v. Cambria Iron Co.***, 185 U.S. 403, 437 [(1902)]. At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby " 'appris [ing] the public of what is still open to them,' " ***Markman v. Westview Instruments, Inc.***, 517 U.S. 370, 373 [(1996)], in a manner that avoids "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims," ***United Carbon Co. v. Binney & Smith Co.***, 317 U.S. 228, 236 [(1942)]. The standard adopted here mandates clarity, while recognizing that absolute precision is unattainable. It also accords with opinions of this Court stating that "the certainty which the law requires in patents is not greater than is reasonably, having regard to their subject-matter." ***Minerals Separation, Ltd. v. Hyde***, 242 U.S. 261, 270 [(1916)].

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 898–99 (2014).

AstraZeneca argues Mylan cannot meet its burden of proving that the claims of the patent-in-suit are indefinite by clear and convincing evidence under a construction of "pharmaceutical composition" that does not require Dr. Smyth's "stability attributes." *See* [Doc. 164-1 at 21–22].

In response, Mylan argues that even if this Court concludes that "pharmaceutical composition" does not include its own stability requirement, there will remain issues of fact as to whether a POSA would understand the boundaries of that term.

Like the issues raised above, these issues must also be resolved at trial. Therefore, the Court **DENIES** AstraZeneca's motion for summary judgment on this issue.

B. Mylan's Motion for Partial Summary Judgment

Mylan moves this Court to grant partial summary judgment in their favor with respect to Count I of AstraZeneca's complaint because AstraZeneca does not allege and cannot show that Mylan committed an act of infringement under the provisions of § 271(e)(2). *See* [Doc. 156]. In support, Mylan asserts that because the FDA approved its ANDA before the patent-in-suit was issued, it could not have committed any act of infringement under § 271(e)(2). Count I of the complaint alleges infringement of the patent-in-suit. *See* [Doc. 1 at 11–13].

i. Law of the Case

First, the law of the case doctrine recognizes that "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." ***Arizona v. California***, 460 U.S. 605, 618 (1983). But because this doctrine was "crafted with the course of ordinary litigation in mind," ***Arizona***, 460 U.S. at

618–19, it does not bar courts from assessing "past holdings based on a different procedural posture" or from applying the proper standard of review at a subsequent stage of the litigation. ***Graves v. Lioi***, 930 F.3d 307, 341 (4th Cir. 2019). Relevant to this case, "a district court retains the power to reconsider and modify its interlocutory judgments . . . at any time prior to final judgment when such is warranted." ***American Canoe Ass'n v. Murphy Farms, Inc.***, 326 F.3d 505, 514–15 (4th Cir. 2003). Moreover, the Fourth Circuit has recognized that "denials of motions to dismiss remain open to trial court reconsideration, and do not constitute the law of the case." ***Krembel v. United States***, 837 F.App'x. 943, 950 (4th Cir. 2020) (quoting ***Perez-Ruiz v. Crespo-Guillen***, 25 F.3d 40, 42 (1st Cir. 1994)); *see also* ***Plotkin v. Lehman***, 1999 WL 259669, at *1 (4th Cir. Apr. 30, 1999) (per curiam).

In this case, the law of this doctrine does not prevent this Court from reconsidering and/or modifying its Memorandum Opinion and Order Denying Defendants' Motion to Dismiss [Doc. 53] should it find such action appropriate.

ii. Infringement

Section 202 of the Patent Act, codified as 35 U.S.C. § 271(e)(2)(A), created an "artificial" act of infringement. ***Eli Lilly***, 496 U.S. at 678. That provision provides in relevant part:

> It shall be an *act of infringement to submit* . . . an application under section 505(j) of the [Federal Food, Drug, and Cosmetic] Act for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial

> manufacture, use or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). It "facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere fact of filing a Paragraph IV ANDA constitutes an act of patent infringement." ***Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc. (Caraco I)***, 527 F.3d 1278, 1283 (Fed. Cir. 2008). Litigation does not have to be delayed until actual sale of an accused product.

An infringement inquiry pursuant to 35 U.S.C. § 271(e)(2)(A) "is focused on a comparison of the asserted patent [claims] against 'the product that is likely to be sold following ANDA approval.'" ***Alcon Research Ltd. v. Barr Labs., Inc.***, 745 F.3d 1180, 1186 (Fed. Cir. 2014) (quoting ***Abbott Labs. v. TorPharm, Inc.***, 300 F.3d 1367, 1373 (Fed. Cir. 2002)). AstraZeneca, as the patentee, bears the burden of proving infringement by a preponderance of the evidence. ***Warner-Lambert Co. v. Apotex Corp.***, 316 F.3d 1348, 1366 (Fed. Cir. 2003).

This Court addresses whether a claim for infringement of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A) can lie where the patent-in-suit issued after Mylan's original ANDA was submitted and AstraZeneca sued Mylan for infringement of the asserted claims prior to Mylan submitting two "Prior Approval Supplements."

The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act ("FDA") and the patent laws to enable general drugs to be more easily approved and to respond to a loss of effective patent life resulting from the requirement that drug products require premarket testing and then must undergo FDA review, actions that consume

significant portions of a patent term. *See* ***Eli Lilly & Co. v. Medtronic, Inc.***, 496 U.S. 661, 669–70 (1990). The Hatch-Waxman Act "str[ikes] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." ***Andrx Pharm., Inc. v. Biovail Corp.***, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

A brand-name drug manufacturer seeking FDA approval for a drug submits a new drug application (NDA) containing, among other things, a statement of the drug's components and proposed labeling describing the uses for which the drug may be marketed. *See* 21 U.S.C. § 355(b)(1), (d). Once the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version by filing an abbreviated new drug application ("ANDA"). *See* §§ 355(j)(2)(A)(ii), (iv). But the FDA cannot authorize a generic drug that would infringe a brand manufacturer's patent.

An applicant submitting an ANDA must certify one of four things: (1) that the drug for which the ANDA is submitted has not been patented (a "paragraph I" certification); (2) that any patent on such drug has expired (a "paragraph II" certification); (3) the date on which the patent on such drug will expire, if it has not yet expired (a "paragraph III" certification); and (4) that the patent on such drug "is invalid or that it will not be infringed by the manufacture, use, or sale of the new drug" for which the ANDA is submitted (a "paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). If the applicant provides a Paragraph IV Certification, the patent holder may file suit under § 271(e)(2)(A). If the patent holder files suit within 45 days, the FDA is barred from approving the ANDA for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may approve the ANDA after that period,

or earlier if the applicant succeeds in showing non-infringement of the patent or in proving the patent's invalidity. Id. § 355(j)(5)(B)(iii)(I).

An ANDA is not a single, discrete document. An ANDA includes ensuing submissions to the FDA. The relevant FDA regulations expressly define ANDA as "the application described under § 314.94, including all amendments and supplements to the application." 21 C.F.R. § 314.3(b). An applicant may submit an "amendment" to an ANDA "that is submitted. . ., but not yet approved." 21 C.F.R. § 314.96(a)(1). A "supplement" occurs after initial approval. 21 C.F.R. § 314-97.

There are different types of supplements, some of which require FDA approval of the supplement itself before the changes to an application they describe can be applied. The FDA regulations describe "major changes" that require supplemental submission and approval prior to distribution of the product made using the change. *See* 21 C.F.R. § 314.70(b). As relevant here, a "Prior Approval Supplement" is considered a "major change" to an ANDA. *See* id.; FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Changes to an Approved NDA or ANDA*, at 9 (April 2004), https://www.fda.gov/media/71846/download.

At the conclusion of the litigation, if a court concludes that the ANDA product does not infringe the asserted patents, then the generic filer lawfully may market its competing product. However, if a court finds infringement, then § 271(e)(4) sets forth the available remedies to the patentee. *See* 35 U.S.C.A. § 271(e)(4).[3] "If the FDA has not approved the

[3] Relevant here is § 271(e)(4)(A), which reads:

> For an act of infringement described in paragraph (2)-- (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not

ANDA before the district court determines that the patent has been infringed, the FDA may not approve the NDA until the effective date specified by the district court under section 271(e)(4)(A). *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb). If the FDA has already approved the ANDA, the district court's order would alter the effective date of the application, thereby converting a final approval into a tentative approval. *See* ***Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.***, 520 F.3d 1358, 1366 (Fed. Cir. 2008); ***Mylan Labs., Inc. v. Thompson***, 389 F.3d 1272, 1281–82 (D.C. Cir. 2004); *see also* S.Rep. No. 98–547, at 46 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2679 ("In the case where an ANDA had been approved, the order would mandate a change in the effective date.")." ***In re Omeprazole Patent Litig.***, 536 F.3d 1361, 1367–68 (Fed. Cir. 2008).

Put simply, the Federal Circuit has recognized that remedies under § 271(e)(4) continue to be available, and an infringement claim continues to be viable, even if the FDA has already approved the ANDA. In such circumstances, the Federal Circuit has held that upon a finding of infringement under § 271(e)(2), approval is rescinded until the expiration of the patent, including any associated periods of exclusivity, such as pediatric exclusivity. *See* ***id***. at 1367–69.

In this case, the patent-in-suit is a patent "for a drug ... the use of which is claimed in a patent," 35 U.S.C. § 271(e)(2)(A), as contemplated in the Act even though it issued after Mylan filed its ANDA. Mylan subsequently amended its ANDA with two "Prior Approval Supplements." The first "Prior Approval Supplement" is dated May 25, 2022, and

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> earlier than the date of the expiration of the patent which has been infringed. . . .

provides "for revisions to the drug product specification, specifically the specification for leachables." *See* [Doc. 165-3 at 2]. The second "Prior Approval Supplement is dated June 28, 2022, and provides a "revision to the valve specification for extractables. . . ." *See* [Doc. 165-5 at 2]. However, Mylan did not file a Paragraph IV Certification with respect to the patent-in-suit.

The infringement analysis under § 271(e)(2)(A) "require[s] consideration of the amended ANDA." ***Ferring B.V. v. Watson Labs., Inc.-Fla.***, 764 F.3d 1382, 1390 (Fed. Cir. 2004). "There is no support for the proposition that the question of infringement must be addressed solely based on the initial ANDA filing, given that the statute contemplated that the ANDA will be amended as a matter of course." ***Id***. Thus, amendments to an ANDA can constitute an act of infringement under § 271(e)(2)(1). *See* ***Bristol-Myers Squibb Co. v. Royce Labs., Inc.***, 69 F.3d 1130, 1135 (Fed. Cir. 1995) (holding that by amending an ANDA to include a Paragraph IV certification, the applicant "committed an act of infringement under the Hatch-Waxman Act because it sought 'to obtain approval ... to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent ... before the expiration of such patent'" (alterations in original) (quoting 35 U.S.C. § 271(e)(2)(A)).

Here, it is undisputed that Mylan supplemented the ANDA by submitting two "Prior Approval Supplements" after the patent-at-suit issued. Such an act is a qualifying act of infringement under § 271(e)(2)(A). Clearly there is a patent in place and clearly an ANDA infringes it. If courts can reset the date for an ANDA approved after the patent is filed, this

Court should be able to reset the date for a case like this. This Court refuses to leave the patentee with no recourse under § 271(e)(2).

A filer of an ANDA is therefore subject to a 35 U.S.C. § 271(e)(2)(A) infringement claim on a patent that issues after the filing of the ANDA, but before FDA approval. The resolution of infringement claims under § 271(e)(2)(A) for patents that issue after an ANDA is submitted, but before it is approved, "facilitates the early resolution of patent disputes between generic and pioneering drug companies" in accordance with the purpose of § 271(e)(2). ***Caraco I***, 527 F.3d at 1283.

Several district courts have held that a Paragraph IV Certification is not required to sustain a § 271(e)(2) claim. *See* ***Impax Labs., Inc. v. Aventis Pharm. Inc.***, 468 F.3d 1366, 1372–73 (Fed. Cir. 2006) (§ 271(e)(2) action proper without Paragraph IV Certification); ***Tadeka Pharm. Co., Ltd. v. Twi Pharms., Inc.***, 2013 WL 12164680, at *21 (N.D. Cal. May 20, 2013) (collecting cases).

In this case, it is clear that AstraZeneca can properly obtain prospective relief in the form of an order resetting the date of approval to the date the infringed patent and associated exclusivities expire if this Court finds Mylan's ANDA infringes. This Court finds there is a genuine issue as to material facts and **DENIES** Mylan's motion for summary judgment.

IV. Conclusion

For the foregoing reasons, this Court **DENIES** AstraZeneca's Motion for Summary Judgment [**Doc. 164**] and Defendants' Motion for Partial Summary Judgment [**Doc. 156**].

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record.

DATED: December 5, 2022.

JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE